

REMARKS/ARGUMENT

Description of amendments

Claims 21, 30 and 57 are currently amended. Claims 1, 5-9, 11, 12, 14 16-31, 57-62 and 65-70 are pending after entry of this Amendment, of which Claims 6, 7, 11, 12, 14, 17, 20, 66 and 68-70 are withdrawn as being directed to a non-elected species. No new matter is introduced by this Amendment.

Applicant respectfully requests reconsideration and reexamination in view of the foregoing claim amendments and remarks presented below.

Rejections under 35 U.S.C. §112

Claims 21-31 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. With regards to Claim 21, the Official Action has concluded that there is no written description support for deflating the balloon in preparation for the intended use of the balloon. Applicants traverse this rejection for the following reason.

Applicants' description explains the problems associated with balloons used to deliver coated stents, and/or combinations of coated balloons and stents. For example, the description explains that sometimes a "sticky" or "tacky" surface of a balloon can delaminate a coated stent, which presents the need for minimizing the damage caused to a coated stent by the balloon. The description then concludes that embodiments of the invention provide for methods to "modify the balloon to achieve this as well as other results". *See* Para. [0004] - [0006] of the published application. In the detailed description, "embodiments of the present invention" are said to include mounting a coated stent on a coated balloon to achieve a "dual mode delivery". In this embodiment, an embedded drug can be delivered immediately before, during or after stent deployment. *See* Para. [0023].

As best understood, Claims 21 and 62 stand rejected under Section 112, first paragraph because it is not believed that the inventors were in possession of an invention that included deflating a balloon in preparation for its intended use, or deflating the balloon at any time. The Official Action states that the inventors were only in possession of reducing the balloon size during the modification process or during/prior to the drying process. Applicants disagree.

Obviously, in order to practice the method according to the embodiment of invention described at paragraph [0023], the balloon would not only need to be coated according to the invention, but also deflated so that the stent can be received on the balloon and the balloon catheter with stent delivered to the sight so as to provide a “dual mode delivery” balloon catheter. Stated differently, the objective, i.e., achieving a dual mode delivery without the drawbacks discussed in the background, would never have been realized or appreciated by the inventors if they only possessed an inventive method for modifying a balloon. The rejection under Section 112 therefore cannot stand because it ignores an explicit objective of invention, as well as a description that sets forth the inventive steps needed to achieve this objective. Accordingly, one of ordinary skill in the art would have concluded in light of the dual mode delivery description that the inventors were clearly in possession of the invention set forth under Claims 21 and 62. For at least this reason, Applicants respectfully request that the rejection under Section 112, first paragraph, for Claims 21-31 and 62 be withdrawn.

Rejections under 35 U.S.C. 102(b)

Claims 21, 24-26, 28-29, 31, 57, and 67 are rejected under 35 U.S.C 102(b) as being anticipated by Barry et al. (U.S. Publication 2002/0037358). Claims 21 and 24 are also rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent 5,674,192).

Barry et al. discloses a coating for a balloon that includes first applying a polymer, allowing that polymer to dry, then applying a solution containing a drug. The solution is impregnated in the polymer layer. According to Example 9 of Barry, the polymer layer is applied to the inflated balloon. Sahatjian also discloses a balloon that is coated by a polymer layer followed by a substance contained in a fluid carrier. In the case of Sahatjian, the polymer layer, hydrogel, is said to act as a sponge so that the drug in aqueous solution form can be squeezed out when the balloon is expanded. See Sahatjian, col. 6, ll. 35-50. In each of these cases, the polymer coatings are applied to nonporous balloon material, and the substance is impregnated into this coating, but not the supporting balloon membrane.

Claim 21 is directed to a method of modifying a balloon of a catheter assembly, including inflating a balloon of a catheter assembly to an inflated state, the balloon having a wall membrane enclosed at one end of the catheter assembly such that the enclosed wall membrane

allows the balloon to inflate and deflate on the catheter assembly and applying a substance to an outer surface of the balloon to deposit the substance within the wall membrane. Claims 29 and 30, dependent from Claim 21, recite that the wall membrane is made from a porous material (Claim 29), and comprises pores formed in a non-porous material (Claim 30), respectively. Support for Claims 21, 29 and 30 may be found at paragraphs [0011] and [0012] of the published application.

As best understood, Claim 21 stands rejected as anticipated based in part on the view that Barry or Sahatjian disclose drying or impregnating a substance within the membrane of a polymer layer previously applied to the balloon material. Applicants traverse this rejection for the following reason. Claim 21 recites a method whereby the substance is deposited within a wall membrane that is enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly. Barry or Sahatjian taken alone, or in combination with the other art of record neither teaches nor discloses depositing a substance within a wall membrane that is enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly. Rather, the cited art show a polymer coating being applied to a non-porous material, followed by a fluid layer. As a non-porous balloon material is used, neither the polymer coating nor the fluid layer are deposited within a wall membrane that is enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly of the cited art. Claim 21 is therefore not anticipated by the art of record, nor would this claim have been obvious over the prior art. For at least this reason, Applicants respectfully request that the rejection of Claim 21 be withdrawn and this claim allowed. Claims 22-31 and 67 depend from Claim 21 and are therefore allowable at least due to their dependence on Claim 21. Withdrawal of the rejections to Claims 22-31 and 67 and allowance of these claims is also requested.

According to the Official Action (page 4), Barry anticipates Claim 29 because Barry teaches impregnating a substance within a polyurethane membrane. Applicants traverse this rejection for the following reason. As noted above, Claim 29 refers to the material from which the balloon was made, not a polymer coating over the material from which the balloon was made. Barry, Sahatjian and the other art of record all apply a polymer coating to nonporous

balloon material. In contrast, Claim 29 recites a method that uses a porous balloon material. Claim 30, directed to a different embodiment, recites forming pores in a nonporous balloon material. In this case, a substance may be deposited in pores formed, e.g., by a laser, in the balloon material. For at least this additional reason, Claims 29 and 30 are not taught or suggested by the art of record.

On page 4 of the Official Action it appears that a “saturated” solution is considered the same as a “dissolved” solution with reference to Claims 25-26. Applicants respectfully point out that a dissolved solution does not mean the same thing as a saturated solution. A “saturated” solution is one in which the maximum amount of substance has been dissolved. Any additional substance added to the solution will not dissolve in the fluid carrier. A “dissolved” solution, in contrast, indicates that more substance can be dissolved in the fluid carrier. Finally, a “super saturated” solution refers to a state where more than the “saturated” amount of substance has been dissolved through, e.g., heating of the fluid carrier.

Claim 57 is directed to a method of modifying a balloon of a catheter assembly including inflating a balloon of a catheter assembly to an inflated state, the balloon having a wall membrane enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly and pores formed in the wall membrane. Support for Claim 57 may be found in paragraphs [0011] and [0012] of the published application. For similar reasons as those given above for Claim 21, 29 and 30, Claim 57 is also not taught or suggested by Barry, nor would this claim have been obvious over Barry or Reiss taken in combination with Evens. Applicants respectfully request withdrawal of the rejection to Claim 57 and allowance of this claim.

Claims 58, 59, 60 and 61 depend from Claim 57 and are therefore allowable at least due to their dependence on Claim 57. Withdrawal of the rejections to Claims 58, 59, 60 and 61 and allowance of these claims is earnestly solicited.

Rejections under 35 U.S.C. 103(a)

Claims 1, 5, 8-9, 19, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al. (U.S. Publication 2003/0032963). Claims 1, 5, 8-9, 19, 22-23, 59-62, and 65

also are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358 in view of Reiss et al. (U.S. Publication 2003/0032963).

Barry, discussed earlier, discloses coating an inflated balloon with a substance, e.g., Example 9 of Barry. The amount of inflation for the balloon is not specified under Barry. Rather, this reference merely discloses that the balloon is "inflated". Reiss describes a balloon that can be wholly or partially inflated before a coating is applied.

Claim 1 is directed to a method of modifying a balloon of a catheter assembly including inflating a balloon of a catheter assembly to an inflated state wherein the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter or size at which the balloon becomes damaged or unsuitable for its intended use of insertion into a patient.

The Official Action has rejected Claim 1 over Reiss, or Reiss in combination with Barry because it is believed that the inflated state recited in Claim 1 would have been obvious over the wholly inflated balloon described in Reiss. As best understood, this conclusion relies on a construction for the recited inflated state that includes any insignificant pressure increase over the wholly inflated balloon described in Reiss. With this construction in hand, the Official Action then concludes that because one of ordinary skill in the art would have expected similar results for a balloon inflated an insignificant amount over wholly inflated, as a balloon that is wholly inflated, Claim 1 would have been obvious. Applicants traverse this rejection for the following reasons.

Applicants description sets forth three inflated states for the balloon: under inflated, intended expanded configuration, and over or hyper-inflated. Intended expanded configuration refers to a range of pressures intended for the planned performance of the balloon. Hyper-inflated refers to a diameter greater than the range of an intended expanded configuration but less than a pressure that will cause damage to the balloon. *See* Para. [0013] of the published application. These three states are defined separately, and treated differently in the examples that follow because when the balloon is in each of these states, the pores in the membrane are opened and/or the available surface area increased to different degrees so that more substance may be deposited. Contrary to the assertion set forth in the Official Action, one of ordinary skill in the

art would not, therefore, have construed hyper-inflated as falling within the range of balloon pressures that produce no noticeable differences from an intended use configuration because the description of these separate states is clearly intended to convey the idea of depositing more or less substance based on the degree of inflation of the balloon. Thus, Applicants submit that the construction adopted in the Official Action is incorrect because it takes no account of the teaching for controlling the amount of deposited substance based on the inflated state of the balloon. Moreover, the cited prior art further supports Applicants' view because it too draws a distinction among an intended use configuration, under-inflated and hyper-inflated state. For example, Reiss refers to an under-inflated and a "wholly" inflated state, which is presumed to be the same as an intended use configuration. Importantly, there is no mention of an over-inflated state, because the art recognizes it as a different state for the balloon. Therefore, for this additional reason the construction for the inflated state in Claim 1 adopted in the Official Action cannot be correct because the prior art also distinguishes between an intended use configuration and a hyper-inflated state.

As one of ordinary skill in the art would recognize that the inflated state of Claim 1, when read in light of Applicants' disclosure, is properly construed as a state that creates a significant expansion of the pores and/or surface area of the membrane, beyond that which exists in an intended use configuration, Applicants further submit that it would not have been obvious in view of Reiss taken alone or in combination with Barry to hyper-inflate a balloon when a substance is being applied because the prior art teaches away from this method. As eluded to in the Official Action, one of ordinary skill in the art would be discouraged from over inflating a balloon because of the risks of causing damage to the balloon. However, Applicants disclosure teaches that these risks can be acceptable because a greater amount of substance can be deposited when the balloon is hyper-inflated.

For these reasons, Applicants submit that no *prima facie* case of obviousness for Claim 1 has been established. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn and Claim 1 allowed.

Even assuming that the Official Action's construction for the inflated state is correct, Claim 1 would still not be obvious over the prior art. As noted above and in the Official Action,

one of ordinary skill would have been discouraged from operating a balloon within the hyper-inflated range as this raises an unacceptable risk of causing damage to the balloon. Therefore, as a safeguard against creating a hyper-inflated state, one of ordinary skill would not have placed a balloon near the maximum acceptable pressure of the intended use configuration range, because a balloon maintained at this upper limit would increase the possibility that the balloon was actually in a hyper-inflated state. Putting the balloon even close to the lower limit of the inflated state of Claim 1, under the Official Action's construction of this term, would therefore have been avoided. Thus, even if the Official Action's construction for the inflated state of Claim 1 were adopted, Claim 1 would not have been obvious because the prior art teaches away from placing the balloon anywhere near a hyper-inflated state.

Claims 5, 8, 9, 16, 19, 62 and 65 depend from Claim 1 and are therefore allowable at least due to their dependence on Claim 1. Withdrawal of the rejections to Claims 5, 8, 9, 16, 19, 62 and 65 and allowance of these claims is earnestly solicited.

Election / Restrictions

New Claims 66 and 78-70 have been withdrawn as being directed to a non-elected species in the Official Action. Thus, Claims 6, 7, 11, 12, 14, 17, 20, 66 and 68-70 now stand withdrawn as being directed to a non-elected species. In light of the foregoing, Applicants respectfully request that Claims 6, 7, 11, 12, 14, 17, 20, 66 and 68-70 be re-entered and allowed, at least because they depend from allowable subject matter.

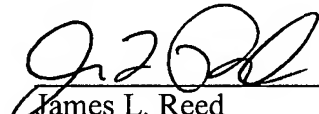
Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0314
jreed@ssd.com



James L. Reed
Attorney for Applicant
Reg. No. 43,877

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